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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/002,211	12/05/2001	Milton D. Goldenberg	018733-1066	5605

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EXAMINER	
CROWDER, CHUN	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 08/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/002,211	GOLDENBERG, MILTON D.	
	Examiner	Art Unit	
	Chun Crowder	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *78-92* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *78-92* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election of immune thrombocytopenic purpura (ITP) and LL2 antibody in the reply filed on 06/15/2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-77 have been previously canceled.

Claims 87-92 have been added.

Claims 78-92 are pending and currently under consideration as they read on the species election of ITP and LL2 antibody.

2. Applicant's cancellation of domestic priority claims to applicants USSN 07/167,077 (now US Patent 5,101,827) and USSN 06/751,877 now (US Patent 4,735,210) is acknowledged.

Applicant's claim for domestic priority is acknowledged. However, the priority applications USSN 09/110,181 (now US Patent 6,331,175) and USSN 07/866,789 (now US Patent 5,776,093) upon which priority is claimed fail to provide adequate support under 35 U.S.C. 112 for claims 78-92 of this application. Specifically, insufficient support was identified for the limitation of "marker associated with a B cell". Consequently, the instant claims have been accorded the priority of the filing date of the instant application, i.e. 12/05/2001.

Therefore, this application repeats a substantial portion of prior USSN 09/110,181 filed 07/06/1998 and USSN 07/866,789 filed 04/07/1992, and add and claim additional disclosure not presented in the prior applications, as indicated above. Since this application names an inventor or inventors named in the prior application, it may constitute a continuation-in-part of the prior application. Should applicant desire to obtain the benefit of the filing date of the prior application, attention is directed to 35 U.S.C. 120 and 37 CFR 1.78.

Therefore, applicant should amend the first line of the specification to indicate the status of the instant application as a continuation-in-part.

Should applicant disagree with the Examiner's factual determination above, it is incumbent upon applicant to provide a showing that specifically supports the instant claim limitations.

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

4. Applicant's IDSs, filed 12/05/2001, 08/27/2002, and 02/09/2004, are acknowledged.

The IDS, filed 12/05/2001, has been considered except reference A11 for which only the English translation of the Abstract has been considered.

The IDS filed 08/27/2002 has been considered.

Applicant has stated under "Relevance of Each Document" on the IDS filed 02/09/2004 regarding two European applications EP 03 07 6875 and EP 03 07 6876 that copies of the documents are not being provided since copies should have been provided directly by WIPO under an exchange program between the PTO, the EPO and the JPO. However, these two references have not been listed on the IDS; and further, there is no benefit claims to any international (PCT) application. Applicant is invited to clarify the relevance of EP 03 07 6875 and EP 03 07 6876. Further, only the US Patent documents listed on IDS filed 02/09/2004 have been considered because applicant has not submitted copies of foreign references of B8-B15 and the non patent literature documents of B16-B27. See 37 C.F.R. 1.98.

5. The application is required to be reviewed and all spelling, TRADEMARK, and like errors corrected.

Trademarks should be capitalized or accompanied by the ™or ® symbol wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent application, the proprietary nature of the trademarks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate correction is required.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 83-92 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 83-92 are indefinite in the recitation of "the therapeutic agent". There is insufficient antecedent basis for this limitation in this claim. The independent claim 78 recites "an antibody or antibody fragment", not "the therapeutic agent".

For examination purposes, claims 83-92 read as dependent on claim 82.

B) Claims 87-92 are indefinite in the recitation of "LL2 antibody" because its characteristics are not known. The use of "LL2 antibody" as the sole means of identifying the claimed antibody renders the claim indefinite because "LL2 antibody" is merely laboratory designation which does not clearly define the claimed product, since different a laboratories may use the same designation to define completely distinct biological materials.

Amending the claims to recite the appropriate Deposit Accession Number or SEQ ID NOs would obviate this rejection. See the rejection under the first paragraph of 35 U.S.C. 112 for the deposit of biological materials below.

C) Applicant is reminded that any amendment must point to a basis in the specification so as not to add new matter. See MPEP 714.02 and 2163.06.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 87-92 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that the LL2 antibody is required to practice the claimed invention. As a required element, it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 USC 112, a deposit of the hybridoma, which produces this antibody, may satisfy first paragraph. See 37 CFR 1.801-1.809.

If the deposit has been made under the terms of the Budapest Treaty, an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the hybridoma has been deposited under the Budapest Treaty and that the hybridoma *will be irrevocably and without restriction or condition released to the public upon the issuance of a patent* would satisfy the deposit requirement made herein. See 37 CFR 1.808.

Further, the record must be clear that the deposit will be maintained in a public depository for a period of 30 years after the date of deposit or 5 years after the last request for a sample *or for the enforceable life of the patent whichever is longer*. See 37 CFR 1.806. If the deposit has not been made under the Budapest treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature must be made, stating that the deposit has been made at an acceptable depository and that the criteria set forth in 37 CFR 1.801-1.809, have been met.

If the deposit was made after the effective filing date of the application for a patent in the United States, a verified statement is required from a person in a position to corroborate that the hybridoma described in the specification as filed are the same as that deposited in the depository. Corroboration may take the form of a showing of a chain of custody from applicant to the depository coupled with corroboration that the deposit is identical to the biological material described in the specification and in the applicant's possession at the time the application was filed.

Further, amendment of the specification to disclose the date of deposit and the complete name and address of the depository (ATCC.10801 University Boulevard, Manassas, VA 20110-2209) is required as set forth in 37 C.F.R. 1.809(d).

10. Claims 78-92 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a *Written Description*, New Matter rejection.

The terms "a marker associated with a B cell" recited in claims 78-92 are not supported by the original disclosure or claim as filed.

Applicant's amendment, filed 03/01/2006, directs to support to page 7, lines 5-10, page 9, lines 2-10, and page 12, lines 30-35.

However, the specification as filed does not provide sufficient written description of the above-mentioned "limitations". The specification does not provide sufficient support for a marker associated with a B cell. The specification only disclose LL2 monoclonal antibody that target the spleen cell; the instant claims now recite any antibody specific to a marker associated with a B cell, which were not clearly disclosed in the specification. Therefore, the claims represent a departure from the specification and claims originally filed. Applicant's reliance on generic disclosure of antibodies and possibly a single or limited species do not provide sufficient direction and guidance to the features currently claimed (antibody specific for a marker associated with a B cell). It is noted that a generic or a sbu-generic disclosure cannot support a species unless the species is specifically described. It cannot be said that a subgenus is necessarily described by a genus encompassing it and a species upon which it reads. See In re Smith 173 USPQ 679 683 (CCPA 1972) and MPEP 2163.05.

Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the new matter in the response to this Office Action.

Alternatively, applicant is invited to provide sufficient written support for the "limitations" indicated above. See MPEP 714.02, 2163.05-06 and 2173.05 (i).

11. Claims 78-92 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The following *written description* rejection is set forth herein.

Claim 78-92 recite "an antibody or antibody fragment specific to a marker associated with a B cell" as part of the invention.

There is insufficient written description in the specification as-filed of "an antibody or antibody fragment specific to a marker associated with a B cell" as recited in the instant claims.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. (See Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, especially page 1106 3rd column). A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. MPEP 2163 II.A.3a.ii.

The claims recite a genus "an antibody or antibody fragment specific for a marker associated with a B cell" as part of the invention without providing a physical structure or testable functional activity for the "a marker associated with a B cell".

The genus of the "an antibody or antibody fragment specific to a marker associated with a B cell" is therefore extremely large. Applicant has disclosed only a monoclonal LL2 antibody that targets the spleen cell (e.g. see page 12 of the instant specification). Thus applicant has disclosed only a limited species of "an antibody or antibody fragment specific to a marker associated with a B cell", namely the monoclonal LL2 antibody. The claimed antibody specific to "a marker associated with a B cell" lack a common structure essential for the function and the claims do not require any particular structure basis or testable functions be shared by the instant antibody specific to "a marker associated with a B cell".

For example, Youinou et al. (Autoimmunity Reviews. 2006. 5:215-221) teach B lymphocytes endow diverse functions within the immune system and B cell receptor editing is essential in preventing autoimmunity, and the transduction machinery is raised by CD19 and CD21 and dampened down by CD22, CD72, and CD5.

The reliance on the disclosed limited number of known antibodies specific for spleen cells does not support the written description of any "antibody or antibody fragment specific to a marker associated with a B cell". In addition, an antibody fragment can be any one of the constant regions (CH1-3) and also may be the hinge region. However, the language also reads on small amino acid sequences which are incomplete regions of the constant region of the antibody. There is no written support in the specification for linking the variable region to any or all of the myriad "antibody fragment" which are encompassed within this language.

There is no representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties regarding the claimed "an antibody or antibody fragment specific to a marker associated with a B cell" in the instant specification.

Mere idea or function is insufficient for written description; isolation and characterization at a minimum are required.

It does not appear based upon the limited disclosure of a monoclonal LL2 antibody alone that Applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the limited number of species disclosed and the extensive variation permitted within the genus of "an antibody or antibody fragment specific to a marker associated with a B cell".

"Adequate written description requires a precise definition, such as by structure, formula, chemical name or physical properties, not a mere wish or plan for obtaining the claimed chemical invention." Regents of the University of California v. Eli Lilly and Co. 43 USPQ2d 1398 (Fed. Cir. 1997).

The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter of the claim. Id. 43 USPQ2d at 1406.

In the absence of disclosure of relevant, identifying characteristics of the "an antibody or antibody fragment specific to a marker associated with a B cell", there is insufficient written disclosure under 35 U.S.C. 112, first paragraph.

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 1115).

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. Claims 78-92 are rejected under 35 U.S.C. 102(b) as being anticipated by Goldenberg (WO 93/19668) (see entire document) as evidenced by Goldenberg (US Patent 6,183,744).

Goldenberg (WO 93/19668) teaches a method of treating immune diseases such as ITP in a subject by using monoclonal LL2 antibody (see entire document, particularly Detailed Description of the Invention on pages 6-24). Further, Goldenberg teaches that the antibody can be conjugated to a therapeutic agent such as cytotoxic agent, radioisptope, and/or a drug; and the antibody can be used as a whole antibody or antigen binding fragments including Fab, Fab', $F(ab')_2$, and/or Fv (e.g. see pages 4-14, in particular).

As evidenced by Goldenberg (US Patent 6,183,744), LL2 antibody is specific for B cell marker CD22.

Therefore, the reference teachings anticipate the claimed invention.

14. Claims 78-92 are rejected under 35 U.S.C. 102(b) as being anticipated by Hansen et al. (US Patent 5, 443,953) (see entire document).

Hansen et al. teach a method of treating a mammal suffering from an immune disease such as ITP by administering an antibody or antibody fragment (e.g. Fab) including LL2 antibody specific to a B cell marker e.g. CD22 (see entire document, particularly Detailed Description and claims 12-14). Further, Hansen et al. teach that the antibody can be conjugated to a therapeutic agent such as cytotoxic agent, radioisptope, and/or a drug (e.g. see column 18, in particular)

Therefore, the reference teachings anticipate the claimed invention.

15. Claims 78-92 are rejected under 35 U.S.C. 102(e) as being anticipated by Golderberg et al. (US Patent 7,074,403) (see entire document).

Golderberg et al. teach methods of treating autoimmune disorders such as ITP using antibody specific for a B cell antigen such as CD22 (see entire document, particularly Detailed Description on columns 2-13 and claims 1-20). Further, Goldenberg et al. teach that the antibody can be conjugated to a therapeutic agent such as cytotoxic agent, radioisptope, and/or a drug; and the antibody can be used as a whole antibody or antigen binding fragments including Fab, Fab', $F(ab')_2$, and/or Fv (e.g. see columns 3-4, in particular).

Therefore, the reference teachings anticipate the claimed invention.

16. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s).

See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

17. Claims78-92 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-140 of US Patent 6,653,104, and claims 1-20 of US Patent 7,074,403.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant and copending claims are drawn to the same or nearly the same methods of treating an immune disease by administering the same or nearly the same antibodies specific to B cell markers. The copending methods rely upon the same or obvious variants of the same antibody specific for CD22; thereby rendering the copending claims anticipatory or obvious over one another.

18. Claims 78-92 are directed to an invention not patentably distinct from claims 1-17 of commonly assigned claims 1-20 of commonly assigned US Patent 7,074,403 for reasons stated above.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned US Patent 7,074,403, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

19. No claim is allowed.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chun Crowder whose telephone number is (571) 272-8142. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chun Crowder, Ph.D.
Patent Examiner
August 1, 2006

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